

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

IN RE APPLICATION OF: ANGEL ET AL. SERIAL No. 09/767,821 FILED: JANUARY 24, 2001 FOR: PROCESS FOR PREPARING WATER-SOLUBLE OR WATER-DISPERSIBLE POLYETHER-CONTAINING POLYMERS AND THE USE THEREOF AS COATING AGENTS, BINDERS AND/OR FILM-FORMING EXCIPIENTS IN PHARMACEU- TICAL DOSAGE FORMS OR PACKAGING MATERIALS OR AS ADDITIVES IN COSMETIC, DERMATOLOGICAL OR HYGIENIC PREPARATIONS	DOCKET No.: PF++51162 CONFIRMATION No.: 2188 GROUP ART UNIT: 1617 EXAMINER: S. KANTAMNENI
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Honorable Commissioner
for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF PURSUANT TO 37 C.F.R. §41.41

Sir:

The following remarks are in reply to additional arguments made in the Examiner's Answer dated April 04, 2007. To the extent that the Examiner has merely reiterated the arguments made in the final Office action, appellants' stand by the position taken in their main Brief on Appeal.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 14.1437. Please credit any excess fees to such deposit account.

Respectfully submitted,
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R E M A R K S

It is respectfully noted that the Examiner's Grounds of Rejection on pages 3 to 5 of the Answer are a copy of the text included in the final action of April 06, 2006, and the Examiner's Response to appellants' Argument on pages 5 and 6 of the Answer essentially copies parts of these Grounds of Rejection. Accordingly, the Examiner's position is essentially addressed in appellants' Brief on Appeal and the respective explanations and remarks are herewith reiterated.

The Examiner draws the motivation to combine the references relied upon in the rejection under Section 103(a), on the one hand, from an *"expectation of controlling the properties such as polydispersity of the graft polymers"*¹⁾ and, on the other hand, from an *"expectation of controlling the viscosity buildup during polymerization and further having a better control of MW of the polymer."*²⁾ However, as previously acknowledged by the Examiner: *"'457 teaches that liquid and solid polyethylene glycol function as a chain transfer agents [sic] because both produce graft copolymers."*³⁾⁴⁾

The procedure described in **GB 922,457** employs polyethylene glycols as starting materials. As such, the reaction mixture encountered in the procedure of **GB 922,457** contains an abundance of chain transfer agent(s). A person of ordinary skill in the art could, therefore, not reasonably expect that the addition of further chain transfer agent to the reaction mixture of **GB 922,457** would have any notable effect on the polydispersity, or would allow a control of the molecular weight, of the graft copolymer obtained in accordance with the procedure of **GB 922,457**. In fact, **GB 922,457** mentions: *"[T]he unreacted polyalkylene glycol can be separated from the graft copolymer, for example, by repeatedly dissolving and precipitating the polymer"*⁵⁾ which indicates that chain transfer conditions due to the presence of the polyalkylene glycols prevail throughout the graft polymerization reaction.

1) Cf. page 5 of the Examiner's Answer, last two lines before "(10) Response ..."

2) Cf. sentence bridging pages 6 and 7 of the Examiner's Answer.

3) Advisory action dated August 24, 2006, Continuation Sheet (PTO-303) lines 19 and 20.

4) Cf. also appellants' remarks on pages 6 and 7 of the main Brief on Appeal dated December 06, 2006.

5) Cf. page 2, indicated lines 10 to 16, of **GB 922,457**.

The Examiner's position that *"it is not relevant if other compounds can also provide labile hydrogen atom [sic]"*⁶⁾ is deemed to be in error. As clearly explained by *Wu et al.*, any compound which provides a more labile hydrogen atom acts as a chain transfer agent. Accordingly, it would be appreciated by a person of ordinary skill having the teaching of *GB 922,457* and the disclosure of *Wu et al.* before him that the reaction mixture of the British reference already contains "chain transfer agent."⁷⁾

GB 922,457 points out: *"that the grafting of the monomers along the polyalkylene chains is induced by means of a radical-forming chain transfer mechanism. To improve the probability of transfer, it is preferred to polymerize in homogeneous phase in the absence of additional solvents."*⁸⁾ In the procedure of *GB 922,457*, polyalkylene glycol chains accordingly act as a "grafting base." A person of ordinary skill in the art would therefore reasonably expect that a PEG-300, as is employed as a chain transfer agent in the polyvinyl pyrrolidone homopolymerization of *Wu et al.*, acts as a "grafting base" in the procedure of *GB 922,457*. However, under those circumstances any PEG-300 which is introduced into the reaction mixture of *GB 922,457* is converted into the graft copolymer and can, therefore, not serve to control the viscosity buildup as the Examiner would have it.

The Examiner's position that a person of ordinary skill in the art would have been motivated by an *"expectation of controlling the properties such as polydispersity of the graft polymers"*¹⁾ or by an *"expectation of controlling the viscosity buildup during polymerization and further having a better control of MW of the polymer,"*²⁾ is therefore not deemed to be well taken.

Additionally, the Examiner newly argued that *Wu et al.*'s *"process of polymerization will result in a mixture of homopolymers, and graft polymers because vinyl pyrrolidone monomer would also graft onto the PEO chain, since the radical formed on PEO chain will also initiate polymerization of vinylpyrrolidone."*⁹⁾ The rationale to support a rejection under 35 U.S.C. 103 may rely on logic and sound scientific

6) Page 8, lines 7 and 8, of the Examiner's Answer.

7) Cf. the Examiner's remarks on page 9, lines 1 to 5, of the Examiner's Answer.

8) Cf. page 2, indicated lines 18 to 24, of *GB 922,457*.

9) Cf. page 7, center paragraph, of the Answer. See also last paragraph on that page.

principle.¹⁰⁾ However, when an examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory must be provided.¹¹⁾ It is respectfully urged that Examiner's theory lacks any evidentiary support. Also, the technical information which is available from the references render the validity of the Examiner's theory highly questionable.

It is pointed out in the British reference that additional solvents interfere with the chain transfer reaction underlying the formation of the vinyl ester / polyalkylene glycol graft copolymers.¹²⁾ Such an additional solvent, namely water, is however used in abundance in the polyvinyl pyrrolidone homopolymerization of *Wu et al.*¹³⁾ The amounts of water which are employed in accordance with the process of *Wu et al.* would reasonably be expected, in light of the statements found in the British reference, to hinder if not inhibit any grafting of vinylpyrrolidone onto the PEG chain, especially since the polymerization conditions employed in accordance with *Wu et al.*'s process favor the formation of polyvinyl pyrrolidone homopolymer. The teaching of *WU et al.* certainly contains nothing which could reasonably be taken to suggest or imply the formation of any graft as alleged by the Examiner. Notably, the polymer solutions obtained in Examples 1 to 3 of *Wu et al.* are described to contain PEG with no mention being made of any grafts.¹⁴⁾ It should also be borne in mind that *Wu et al.* are concerned with the preparation of a polyvinyl pyrrolidone having a narrow molecular weight distribution and the formation of a grafted product as asserted by the Examiner would be counterproductive to the purpose underlying *Wu et al.*'s procedure since a mixture of a homopolymer and a graft copolymer would exhibit an increased polydispersity.

The foregoing further emphasizes that the Examiner errs finding that the polymerization conditions of *GB 922,457* are comparable with the conditions of *Wu et al.* ¹⁵⁾

10) *In re Soli*, 317 F.2d 941, 137 USPQ 797 (CCPA 1963).

11) *In re Grose*, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979).

12) Cf. page 2, indicated lines 21 to 24, of *GB 922,457*.

13) Cf., e.g., col. 2, indicated lines 4 to 7, of *US 5,338,814*.

14) Cf. the Table in col. 4, indicated lines 20 to 28, of *US 5,338,814*.

15) Cf. page 8, lines 21 to 22, of the Examiner's Answer.

C O N C L U S I O N

In light of the foregoing reasons and explanations as well as the arguments already presented by appellants in their Brief dated December 06, 2006, appellants respectfully reiterate their request that the Examiner's final rejection of Claims 1 to 3, 10 and 18 to 21 under 35 U.S.C. §103(a) as being unpatentable in light of the teaching of **GB 922,457** when taken in view of the disclosure of **Wu et al.** (US 5,338,814) be reversed. Favorable action is solicited.